DXA Reference Data: Status, Issues and Future Needs

Anne C Looker

Centers for Disease Control and Prevention
National Center for Health Statistics

SAFER • HEALTHIER • PEOPLE™

Reference data

- Information about a variable's distribution (mean, SD, range)
- Usually based on an average group of individuals
- Used to set thresholds for normal/abnormal
- Uses in bone densitometry:
  - **T-score**
  - **Z-score**

Uses of BMD reference data

T-score: $$\frac{\text{Patient's BMD} - \text{Young-Adult Mean BMD}}{\text{1 SD of Young-Adult Mean BMD}}$$

Z-score: $$\frac{\text{Patient's BMD} - \text{Age-matched Mean BMD}}{\text{1 SD of Age-matched Mean BMD}}$$

T-score Discordance

- Different skeletal sites have different peak bone mass at different times and lose bone at different rates
- Different technologies
- Different ROIs
- Different reference databases have different means and SD (the hip is the only skeletal site with a standardized reference database used by all manufacturers – National Health and Nutrition Examination Survey III)

ISCD
The International Society For Clinical Densitometry
Official Position

Reference Database for T-scores

- Use a uniform Caucasian (non-race adjusted) female normative database for women of all ethnic groups*
- Use a uniform Caucasian (non-race adjusted) male normative database for men of all ethnic groups*
- **The NHANES III database should be used for T-score derivation at the hip regions**

ISCD
The International Society For Clinical Densitometry
Official Position

**Note: Application of recommendation may vary according to local requirements*

Z-score Reference Database

- **Z-scores should be population specific where adequate reference data exist. For the purpose of Z-score calculation, the patient's self-reported ethnicity should be used**

ISCD
The International Society For Clinical Densitometry
Official Position

Potential DXA Reference Database Needs

DXA / pDXA bone densitometers (FDA Product Code KGI):

# manufacturers	**6**
Skeletal sites	**Hip, spine, whole body, forearm, heel, finger**

Potential DXA Reference Database Needs, con't

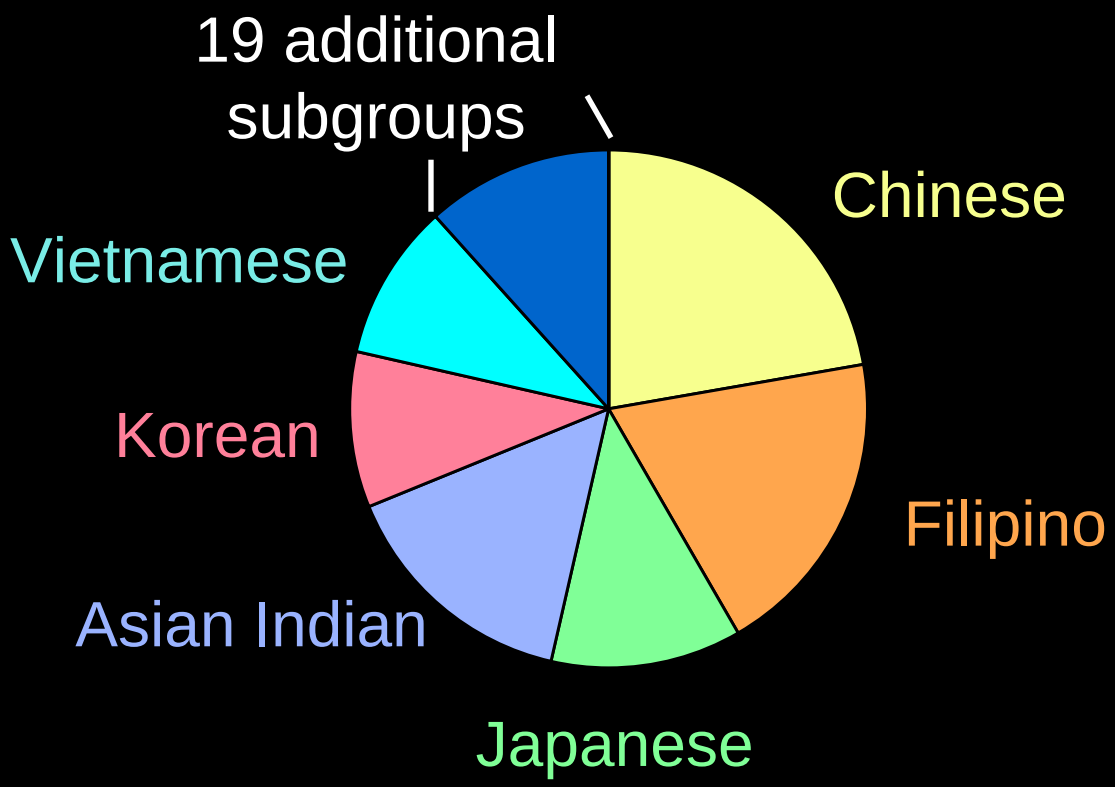
US Census race/ethnic categories:

- White
- Black
- Hispanic
- Asian/Pacific Islander
- Native American

Reference Data Issues: Race-ethnic groups—how specific?

- Can large groupings (Hispanics, Asians) be used?
- Or are subgroup-specific data needed?

U.S. Asian population by origin



SOURCE: U.S. Census Bureau, 2000 Census

Ideal Reference Data Study

- Single study that includes:
  - All relevant skeletal sites
  - All devices
  - All groups

NHANES DXA BMD Data

	Skeletal site	*Sample*	*Method*
NHANES III: (1988-94)	Proximal femur	M&F age 20+ (Whites, Blacks Mex. Americans)	DXA (pencil beam)
NHANES 1999- 2004	Total body	M&F age 8+ (Whites, Blacks Mex. Americans)	DXA (fan beam)
NHANES 2005- ?	Total body Proximal femur Spine (PA)	M&F age 8+* (Whites, Blacks Mex. Americans)	DXA (fan beam)

*Age 8-59 for total body scan

BMD Standardization Formulas

International Committee for Standards in Bone Measurement

- Spine (PA)
- Proximal femur
  - Femur neck
  - Trochanter
  - Ward’s triangle
  - Total femur
- Forearm

Potential strategies to obtain more reference data

- NHANES
- Community-based studies

Advantages to using NHANES to obtain reference data

- Sample represents US population
- Standardized protocol used to obtain sample and collect measurements
- High level of quality control
- Data are publicly available

Barriers to using NHANES for more reference data

- Cost
- General health survey of US population
  - 25-30 conditions assessed
  - Limited time with each respondent
  - Limited space in mobile exam centers

→ Limited ability to assess a particular condition in depth

Community-based studies

- Fixed site using existing facilities (universities, hospitals, etc)
- Community HANES

Example of community-based study: Bone Mineral Density in Childhood Study

- 1554 healthy volunteers age 6-16 years
- Conducted at 5 centers in US
- Skeletal assessments: total body, spine, hip, forearm
- Funded by NICHD

Community HANES
Bridging the gap from national to local surveys

- 2 or 3 defined populations annually
- 2,000 in each sample
- Based on current data or research needs
- Runs parallel to NHANES

Needs for Measurements and Standards Reference data

- What bone health parameters need to be measured, but are difficult or too expensive?
  - **Uniform reference data needed for more skeletal sites, age and race/ethnic groups**
    - » **Standardization formulas needed for instruments not used to collect the bone data**
    - » **Fracture data may be needed to identify appropriate reference group for comparison**
  - **Expense may be prohibitive: need to prioritize**

Critical Challenges for Reference Data

- What are the most demanding challenges for reference data?
  - **Determining priorities for skeletal sites, race/ethnic groups, etc**
  - **Obtaining more detailed fracture data for subgroups**
  - **Obtaining funding**

NIST Measurement Need Datum

- Technology at Issue: DXA
- Technological Innovation at Stake: Uniform reference dataset for more skeletal sites and demographic groups to improve diagnosis consistency; continue efforts on standardization formulas to permit widespread use of uniform reference databases; more fracture data.
- Technical Barrier to the Innovation: Expense of obtaining uniform reference data for additional skeletal sites and demographic groups; fracture data may not exist for all relevant groups

NIST Measurement Need Datum, con't

- Potential Solutions to Problem: Conduct community-based studies using strictly standardized protocols; build support/submit proposal to modify current NHANES DXA component; continue efforts on standardization formulas; conduct community-based studies of fracture in subgroups and/or more detailed analyses of record-based systems
- Potential Providers of Solutions: Government, academia, industry